

Ophthalmic Technologies Inc.
510(k) Submission
i-scan Ophthalmic Ultrasound System

MAY 13 1996

510(K) Summary

(1) Submitter Information:

Name: Ophthalmic Technologies, Inc., Inc.
Address: 37 Kodiak Crescent, Unit 12, Downsview,
Ontario Canada M3J 3E5
Telephone Number: 416-631-6932
Contact Person: Dr. George Myers, 201-438-2310

(2) Names:

Trade: i-scan
Common Usual Name: Ophthalmic A, B, and Biometry
ultrasound system.
Classification Name: System, Imaging, Ultrasonic,
Ophthalmic

(3) Classification, Panel
Class II, 90HPR

(4) Predicate Devices:

- (a) Sonomed Model A2500
- (b) Biophysic Ophthascan B

(5) Description

The OTI i+tech "i-scan" ultrasound system is a multi-purpose personal-computer-based ultrasonic diagnosis system for ophthalmic applications. It includes three separate transducers which provide:

1. A Biometry X-mode for measurement of axial length, using a focused probe which can be hand-held or placed in a tonometer-holder. The operator has a choice of automatic measurement (in which the system automatically finds the critical structures in the eye and makes the measurements) or manual (in which the A-scan is presented on a screen and the operator selects the points for the measurements).

2. An A-scan mode for observation and measurement of the internal structures in the eye, with its own hand-held probe.

3. A B-scan mode, using a hand-held motor-driven transducer, permitting visualization of internal structures in the eye.

(In X-mode, the system also performs IOL calculations with a choice of several algorithms.

(6) Intended Use

The OTI i+tech "i-scan" ultrasound system is intended to both visualize the interior of the eye by means of ultrasound and to make measurements inside the eye, including the measurement of axial length for determination of IOL power.

(7a) Predicate Devices

The OTI i-scan has as predicate devices Sonomed Model A2500 ultrasound system and the Biophysic Ophthascan B system.

(7b) Testing

(The OTI i-scan has undergone both clinical and bench testing. In the clinical tests, it was compared with one of the predicate devices on ten eyes, and the tests showed that its accuracy is equivalent to that of the predicate device. The bench tests include tests on a phantom in both automatic mode (for IOL measurement) and manual mode (for A and B mode measurements), tests for the Canadian Standards Association, Electromagnetic Radiation tests, and Transducer Emission Tests. Results of these tests are in the testing section. All materials in contact with the eye have been tested for biocompatibility. Test reports are included.

These tests all show that the OTI i-scan is safe and effective for its intended use.